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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,408	12/07/2001	John J. Castellot JR.	MBI-004CN	6101

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/010,408

Applicant(s)

CASTELLOT, JOHN J.

Examiner

James Martinell

Art Unit

1631

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 22-47, 51-57, 59 and 61-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 48-50, 58 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1631

Claims 22-47, 51-57, 59, and 61-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 9 (filed July 1, 2003).

Neither one of the GenBank® searches has been considered because they are not publications. In addition, GenBank® Accession No. U80818 has not been considered because no copy of the reference is in this file or in the parent file Serial No. 09/044,273.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 13-21, 48-50, 58, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "at least about 60% homologous to" (claims 1, 8, and 13) is vague and indefinite because the metes and bounds of the claims are not clear. For example, it is not clear whether 50% homology is included or excluded.
- (b) The recitation of "HICP" (claims 1, 7, 10, 20, 21, 48, 49, 50, and 58) is vague and indefinite. The term does not describe a structure that can be used to determine whether a given molecule is embraced by the claims.
- (c) The recitation of "specifically detects" (claim 7) is vague, indefinite, and incomplete because specificity of detection depends upon the presence of other, unmentioned, molecules within the reaction mixture.

Art Unit: 1631

- (d) The recitation of "modulate cell proliferation" is vague and indefinite because the instant application does not distinguish between modulation and non-modulation.
- (e) The recitation of "modulate a growth factor signaling pathway" (claim 13) is vague and indefinite because the instant application does not distinguish between modulation and non-modulation.
- (f) The recitation of "modulate the activity of CTGF or PDGF" (claim 13) is vague and indefinite because the instant application does not distinguish between modulation and non-modulation.
- (g) The recitation of "CTGF" (claim 13) is vague and indefinite because the term is not defined. The substitution of the full term is suggested.
- (h) The recitation of "PDGF" (claim 13) is vague and indefinite because the term is not defined. The substitution of the full term is suggested.
- (i) The recitation of "modulate a heparin-induced response in a heparin-responsive cell" (claim 13) is vague and indefinite because the instant application does not distinguish between modulation and non-modulation.
- (j) Claim 48 is vague and indefinite because it claims more than was elected. Only the methods for detecting nucleic acids were included in the elected Group (*i.e.* Group I).
- (k) The recitation of "aberrant modification or mutation of a gene encoding HICP protein" (claim 58) is vague and indefinite because the metes and bounds of the claim are not clear within the context of the claim. The instant application establishes no standard as to what is not aberrant or not a mutation.
- (l) The recitation of "mis-regulation" (claim 58) is vague and indefinite because the instant application does not establish a standard for non-mis-regulation.
- (m) The recitation of "aberrant post-translational modification of a HICP protein" (claim 58) is vague and indefinite because the instant application establishes no standard for post-translational modification.

Art Unit: 1631

Claims 1, 8, 13, and 16-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those sequences recited with specificity, does not reasonably provide enablement for sequences that have 60% homology to certain SEQ ID NOs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. An astronomical number of nucleic acid sequences and polypeptide sequences are embraced by or mentioned in the claims. One of skill in the art would be obliged to perform undue experimentation to determine which variants might have activity and/or use because the instant application does not provide guidance to one of skill in the art as to which types of variants might have activity and/or use. For example, there are about 8×10^{908} sequences with 60% sequence identity to SEQ ID NO: 1, 1×10^{202} sequences with 60% sequence identity to SEQ ID NO: 2, and about 9×10^{399} sequences with 60% sequence identity to SEQ ID NO: 3. The Court of Appeals for the Federal Circuit found that claims reciting polypeptides with multiple amino acid substitutions were broader than the enabling disclosure. See (*Amgen v. Chugai* (18 USPQ2d 1016, Fed. Cir. 1991)).

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-21, 48-50, 58, and 60 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility and no specific, substantial, and credible utility is readily apparent to one of skill in the art given the instant application. The instant application does not disclose enough information about the relationship of the polypeptides mentioned in the claims and any particular condition or disease. The Supreme Court of the United States in *Brenner v. Manson* (148 USPQ 689 (decided March 21, 1966)) has held that in order to meet the utility statute an invention must have a use in its currently available (*i.e.* as of its effective filing date) form. "It was never intended that a patent be granted upon a product, or a

Art Unit: 1631

process producing a product, unless such product be useful." - page 693 (The Supreme Court is quoting *Bremen*, 37 CCPA 1032, 1034, 182 F.2d 216, 217, 86 USPQ 74, 75). "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." - page 695. "But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." - page 696.

Claims 1-21, 48-50, 58, and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the rejection under 35 USC § 101 is incorporated here.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 10, and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bonaldo et al (*Genome Res.* 6: 791 (1996)). Bonaldo et al discloses a DNA that is 99.4% identical to SEQ ID NO: 1, positions 1534-1708 (see Appendix Bonaldo et al attached to this Office action). Thus, the DNA of Bonaldo et al is embraced by the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and

Art Unit: 1631

can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028.

PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.
Primary Examiner
Art Unit 1631**

Attachment: Appendix Bonaldo et al